UNIVERSIDADE DE LISBOA

FACULDADE DE MEDICINA DENTÁRIA

COMPARATIVE ANALYSIS OF CYCLIC FATIGUE BETWEEN NEW AND CLINICALLY USED PROTAPER NEXT™ INSTRUMENTS

Patrícia Simões Quaresma

DISSERTAÇÃO

MESTRADO INTEGRADO EM MEDICINA DENTÁRIA

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Dissertação orientada pelos Prof. Doutor António Ginjeira e

Prof. Doutor Rui F. Martins (FCT-UNL/DEMI)

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"Não há nenhum caminho tranquilizador à nossa espera. Se o queremos, teremos de construí-lo com as nossas mãos."

José Saramago

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RESUMO

INTRODUÇÃO: Tradicionalmente, a instrumentação canalar era feita com limas de aço inoxidável. Para tentar superar a rigidez inerente a estas limas foram introduzidos instrumentos fabricados com Níquel-Titânio (NiTi). A sua superelasticidade e memória de forma oferecem uma maior flexibilidade e resistência, o que faz com que exista uma melhoria na geometria dos canais preparados e uma diminuição no tempo da instrumentação. No entanto, estes instrumentos de NiTi parecem exibir um maior risco de fratura, e porque normalmente ocorre sem sinais visíveis de deformação do metal, a sua prevenção é difícil, podendo comprometer o prognóstico do tratamento. A fratura do instrumento pode ocorrer devido a variações na anatomia do canal, ao tamanho, calibre e geometria, a utilizações prévias, à experiência do operador, entre outros fatores. Existem duas causas principais para a fratura: a fadiga e a torção. A torção ocorre quando o limite elástico do metal é ultrapassado, por exemplo quando a ponta da lima fica presa no canal enquanto o motor continua a rodar. A fadiga ocorre com a lima livre na curvatura de um canal, sujeita a ciclos de tensão/compressão. Clinicamente, a fadiga parece ser a causa mais prevalente de fratura.

A tecnologia M-*Wire*® foi desenvolvida recentemente e difere das ligas de NiTi convencional porque é submetida a um tratamento termomecânico que lhes confere maior resistência à fadiga cíclica, segundo os fabricantes. O sistema ProTaper Next™ foi lançado em 2013 e apresenta um centro de massa e o centro de rotação não coincidentes, uma secção retangular, conicidades progressivas no mesmo instrumento e a tecnologia M-*Wire*®. O fabricante recomenda o uso individual para reduzir o risco de fratura, otimizar a eficiência de corte e evitar o risco de infeção cruzada.

OBJECTIVO: Comparar a resistência à fatiga entre limas usadas clinicamente e limas sem utilizações.

MATERIAIS E MÉTODOS: Foram analisadas 26 limas endodônticas de 25 mm do sistema ProTaper Next™ com várias utilizações clínicas. Pode-se dividir a amostra de acordo com o tipo de lima: X1 (n=9), X2 (n=8) e X3 (n=9). No seguimento dos estudos que têm vindo a ser desenvolvidos na parceria estabelecida entre o departamento de Endodontia da Faculdade de Medicina Dentária da Universidade de Lisboa e o departamento de Engenharia Mecânica da Faculdade de Ciências e Tecnologia da

Universidade Nova de Lisboa foi criado um sistema mecânico em que as limas são submetidas a forças que se assemelham ao canal radicular. De forma a comparar os resultados obtidos com estudos anteriormente realizados, os mesmos parâmetros foram seguidos: o raio de curvatura foi de 4,7 mm, o ângulo de curvatura de 45º, a velocidade de rotação de 300 rpm (a indicada pelo fabricante) e um binário de 4 N.cm. Cada instrumento foi inserido no contra-ângulo acoplado ao micromotor WaveOne™ e submetido ao teste de fadiga. O tempo que a lima demorou a fraturar foi registado com um cronómetro digital, sempre pelo mesmo operador. Em seguida foi calculado o Número de Ciclos à Fratura (NCF), multiplicando o tempo com a velocidade de rotação. Os dados obtidos em relação ao local de fratura e NCF foram estatisticamente analisados pelos testes não-paramétricos de Mann-Whitney U e Kruskal-Wallis e pelo teste paramétrico t-*student* para amostras independentes tendo em conta os resultados dos testes de normalidade Kolmogorov-Smirnov e Shapiro-Wilk previamente aplicados. A significância estabelecida foi de 95%.

RESULTADOS: Através da análise do NCF dos instrumentos, a lima X1 provou ser estatisticamente mais resistente que a X2 e X3, com um valor de p = 0,008. X2 apresentou uma média de NCF superior a X3 mas não estatisticamente significativa. O local de fratura não mostrou diferenças estatisticamente significativas entre os vários tipos de instrumentos, com um valor de p = 0,405. Quando comparados os resultados entre as limas clinicamente utilizadas com as novas, verificou-se uma diminuição na média dos valores de NCF das limas usadas. No entanto, só o instrumento X3 é que provou estatisticamente existir uma diminuição na sua resistência à fadiga com o uso. Por fim, comparou-se o local de fratura entre as limas usadas e novas e para os três tipos de limas houve uma diferença no local de fratura estatisticamente significativa.

DISCUSSÃO: Um dos resultados deste estudo é que existem diferentes resistências à fadiga entre diferentes instrumentos. X1 apresenta-se como a mais resistente, seguida de X2 e X3. A literatura reporta que instrumentos com diâmetros maiores tem uma menor resistência à fadiga em relação a instrumentos de menores dimensões o que corrobora os resultados obtidos. Verificou-se também uma diminuição da resistência à fadiga entre as limas usadas e as novas, sendo que só nos dados da lima X3 é que este resultado foi estatisticamente significativo. Alguns autores defendem que limas submetidas a um uso clínico repetido apresentam uma redução na sua resistência à fadiga. Apenas um artigo foi encontrado na literatura que compara limas ProTaper Next^{TM} novas e usadas. Os resultados mostram que X1 foi a lima com maior incidência de separação entre os instrumentos testados. Uma possível explicação, apresentada pelos autores, para este resultado é o facto de X1 ter sido a primeira lima a ser usada até ao comprimento de trabalho e a instrumentar os três terços do canal, daí X1 ser a lima mais propensa a sofrer fratura por fadiga.

Em relação ao local de fratura das limas, só entre as limas usadas e novas é que houve uma diferença estatisticamente significativa, talvez devido ao facto de que no presente estudo a medição foi feita com uma régua e no estudo de Vaz de 2014 foi feita com uma mesa de coordenadas, o que se traduz em dados mais precisos. Esta diferença no protocolo representa uma limitação no estudo, no entanto a mesa de coordenadas não estava disponível. Outra explicação plausível é de que como a amostra foi previamente sujeita a stress durante o seu uso clínico, fraturas na superfície podem estar presentes influenciando o local de fratura.

Apenas dois estudos foram encontrados cujo objetivo era avaliar a resistência à fadiga das limas ProTaper Next^{TM} sem utilizações. Apesar de os procedimentos experimentais serem diferentes entre si e com o presente estudo, os resultados são semelhantes: X1 provou ser a lima mais resistente, seguida de X2 e X3.

Outros estudos avaliando sistemas de instrumentos endodônticos diferentes estão disponíveis, e não existe um consenso de quantas vezes e durante quanto tempo é que se pode usar uma lima na instrumentação. É de importância referir que os instrumentos recolhidos para este estudo foram operados por diversos clínicos em diferentes casos. Os dentes podem apresentar diferenças na dureza da dentina, no diâmetro, no ângulo e no raio de curvatura. Além disso, o tamanho da amostra é pequeno e heterogéneo dado que as limas foram usadas entre 5 a 8 casos clínicos, o que pode introduzir vieses. No entanto, a padronização das condições experimentais usando dentes naturais é muito difícil dado que nesses testes cada dente só pode ser utilizado uma vez e a trajetória do canal radicular vai-se alterando durante a instrumentação.

É de realçar ainda que a presente amostra foi submetida à esterilização entre 5 e 8 vezes. Este facto pode ter também afetado a resistência à fadiga das presentes limas, já que a esterilização, o hipoclorito de sódio e outras soluções usadas na irrigação e lubrificação durante a instrumentação podem contribuir para uma corrosão adicional e potenciar ou iniciar uma fratura na superfície da lima. Recomenda-se em estudos

futuros a análise de um maior número de limas com um maior controle no seu uso clínico para fornecer uma maior evidência científica.

CONCLUSÃO: Tendo em conta as limitações deste estudo *in vitro*, os resultados sugerem que a resistência à fadiga cíclica diminui após várias utilizações clínicas das limas e é recomendado que os instrumentos sejam cuidadosamente inspecionados antes de cada utilização. A possibilidade de descartar os instrumentos após uma utilização em casos mais complexos deve ser considerada. Os instrumentos de maiores dimensões também apresentaram uma resistência à fadiga mais baixa, portanto estas limas, em particular, devem ser utilizadas com maior precaução. Tendo em conta que os instrumentos endodônticos são amplamente utilizados, existe uma necessidade de padronização dos testes de fadiga para assegurar a uniformidade da metodologia e a comparabilidade dos resultados para um uso clínico mais seguro.

PALAVRAS-CHAVE: ProTaper Next; resistência à fadiga; instrumentos níquel-titânio; usadas clinicamente; endodontia.

ABSTRACT

INTRODUCTION: NiTi instruments were introduced in endodontic instrumentation to overcome the disadvantages of stainless steel files. However, it seems that these files exhibit a higher risk of intra-operative fracture, compromising the outcome of endodontic treatment. The aim of this study is to compare cyclic fatigue resistance between clinically used and new files.

MATERIAL AND METHODS: Twenty-six clinically used ProTaper Next^{TM} files were analyzed. The sample was 9 files of X1, 8 of X2 and 9 of X3. A mechanical device was used to simulate the root canal system and, to compare our data with a previous study, the same parameters were followed. The testing time was registered with a digital chronometer until tip separation occurred. The number of cycles to fracture was calculated multiplying time by rotational speed. Data obtained was statistically analyzed by Mann-Whitney U and Kruskal-Wallis tests or t-student test taking into account the results of the normality tests previously applied. Significance was set at the 95% confidence level.

RESULTS: X1 instrument proved to be statistically more resistant to cyclic fatigue than X2 and X3, respectively. X3 was the only file that showed a significant decrease in the resistance after clinical use. The local of fracture of used and new files was statistically different.

DISCUSSION AND CONCLUSIONS: Within the limitations of this study, the results suggest that resistance to fatigue life diminish after various clinical uses and all instruments should be checked carefully before each use. A single use should be considered in more complex cases. A lower resistance to cyclic fatigue in larger instruments was also shown, so these files should be used with greater care. There is a need for standardization in cyclic fatigue tests of endodontic instruments to ensure the uniformity of methodology and comparable results for a safer clinical use.

KEYWORDS: ProTaper Next; cyclic fatigue; nickel-titanium instruments; clinical use; endodontics.

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1. INTRODUCTION

Endodontology studies not only the form, function, health and diseases of the dental pulp and periradicular region but also their prevention and treatment. Therefore endodontic practice covers etiology, diagnosis and treatment of dental pain and diseases. When dental pulp is diseased or injured apical periodontitis can occur, which is an infection in the periradicular region. The aim of the treatment is to preserve or restore to health periradicular tissues and prevent future infections. This usually means root canal treatment, occasionally in combination with surgical endodontics (European Society of Endodontology 2006).

Root canal treatment includes cleaning and shaping procedures which have the biological objective of removing all pulp tissue, bacteria and endotoxins from the root canal system. Mechanical enlargement of root canal is therefore an important part of endodontic treatment. Properly shaped canals are essential for adequate chemical irrigation and a three-dimensional obturation (Fife *et al.* 2004).

1.1 Nickel-Titanium endodontic instruments

Traditionally, the cleaning and shaping have been performed by using stainless steel hand instruments (also called files). It has long been recognized that the use of these files is associated with undesirable alteration of the root canal morphology during preparation making proper filling of the root canal system difficult. To overcome these unpleasant characteristics, instruments manufactured from Nickel-Titanium (NiTi) alloy were introduced in 1988 to surmount the rigidity (high modulus of elasticity) of stainless steel files (Al-Hadlaq *et al*. 2010).

The shape memory and superelastic properties of NiTi offers a greater flexibility and resistance to torsional fracture and allows the NiTi rotary instruments to be used in a continuous rotation, even in curved root canals, with a low risk of transporting the original canal lumen (Kim *et al*. 2010; Enalghy 2014). Flexibility can be defined as the elastic bending of an endodontic instrument when subjected to load applied at its extremity in a perpendicular direction to its long axis and is influenced by composition and thermomechanical treatment of the alloy as well as instrument geometry, including size and cross-sectional design (Lopes *et al.* 2013).

NiTi endodontic instruments also improved the geometry of the prepared canals providing well-centered canal instrumentation, a decrease in time treatment and the extrusion of less dentin debris. These advantages led to the rapid adoption of rotary NiTi instruments by dental professionals (Al-Hadlaq 2011; Setzer and Böhme 2013).

1.2 When fracture occurs

Despite its increased strength and flexibility, NiTi rotary instruments may exhibit a higher risk of intra-operative fracture within the root canal. Because file failure usually occurs without any visible signs of permanent metal deformation, prevention of this event is difficult (Al-Hadlaq 2011; Pedullà *et al.* 2013).

Instrument fracture is a serious problem and can jeopardize the outcome of the root canal treatment and compromise prognosis of the tooth. Studies show that the incidence of clinically observed instrument fractures ranges from 0,9% to 21% (Nguyen *et al*. 2014). A survey showed that 61,8% of the dentists had experienced complications during or after removal of fractured files. It seems to occur mostly in the apical third of the root canal and the complications most commonly reported in literature are excessive removal of tooth structure, ledges, canal transportation and even root perforation (Castelló-Escrivá *et al.* 2012).

File separation occurs due to variations in the canal anatomy such as radius and angle of curvature, re-curving, dilacerations or dividing canals. Additional factors from endodontic instruments can affect the fracture resistance such as size, taper and cross-sectional geometry, metal surface treatments and metallurgical characterization of NiTi alloys, flexibility and rigidity. The rotational speed, torque, technique, operator experience, previous use, dentin debris and sterilization procedures also have a significant influence on the mechanical behavior of NiTi instruments. Although these factors are often described individually, they act collectively (Yao *et al.* 2006; Aydin *et al.* 2010; Al-Sudani *et al*. 2012; Bhagabati *et al.* 2012).

Many variables may contribute to failure of rotary endodontic instruments but the two main causes are torsional fatigue and cyclic flexural fatigue. Clinically, cyclic fatigue seems to be more prevalent in curved root canals, whereas torsional failure might happen even in a straight canal (Bhagabati *et al.* 2012; Nguyen *et al.* 2014).

More frequently, it is a combination of these two factors that cause fracture in clinical situations (Pedullà *et al*. 2013).

1.2.1 Torsional fatigue

Torsional fatigue occurs when the tip or another part of the instrument is locked in a canal whilst the shank continues to rotate. When the elastic limit of metal is exceeded by torque exerted by the handpiece, fracture of the tip becomes inevitable. Frequently, signs of plastic deformation are visible (Plotino *et al*. 2009; Gambarini *et al*. 2010; Al-Hadlaq 2011). This torsional fatigue is static but dynamic torsion fatigue also exists, which results from frictional forces caused by the resistance of dentin to file cutting (Yao *et al.* 2006). The risk of rotary nickel-titanium instruments to fracture by torsion has been substantially reduced with the introduction of low-torque motors that operate below the elastic limit of the nickel-titanium alloy and the creation of glide paths manually with hand instruments before taking rotary instruments to the working length (Ounsi *et al.* 2007).

1.2.2 Cyclic fatigue

In cyclic fatigue NiTi instruments rotates freely in the curvature and are subjected to repeated tensile and compressive stress, for a prolonged period of time, such that during each rotation the inner surface of the instrument is compressed and the outer surface is under tension (Gambarini *et al*. 2010). This repeated tension/compression cycle will cause cumulative microstructural changes that may lead to fracture of the instrument, and this fracture usually occurs at the point of maximum curvature (Al-Hadlaq *et al.* 2010). Known as cyclic fatigue, this metal fatigue has been seen as the main cause for rotary NiTi instrument separation and seems to be responsible for 50-90% of mechanical failures (Inan *et al.* 2007; Bhagabati *et al.* 2012; Setzer and Böhme 2013; Nguyen *et al.* 2014).

1.2.2.1 Cyclic fatigue tests

Fatigue life is usually tested by measuring the number of rotations of the instrument in an artificial root canal until fracture (Lee *et al*. 2011). The cyclic fatigue resistance comprises the number of cycles that an instrument can endure under a specific loading condition until fracture occurs (Lopes *et al.* 2012). Because the number of cycles to fracture is cumulative, it can be calculated by multiplying the rotational speed by time elapsed until fracture occurs (Lopes *et al.* 2010). This relates to intensity of compressive and tensile stress occurring in the bent portion of the instrument (Lopes *et al.* 2009). The greater the value of NCF (Number of Cycles to Fracture), the greater is its resistance to fracture. Cyclic fatigue tests can be static or dynamic. In static tests the instrument rotates at a fixed length (with no axial oscillation) whereas in the dynamic model the instrument is moved back and forth within the canal (Rodrigues *et al.* 2011).

Several factors can influence the cyclic fatigue resistance of an endodontic instrument subjected to flexural fatigue.

a) Surface finishing

Defects in surface finish resulting from the machining process used for manufacturing NiTi instruments is one of the factors that influence cyclic fatigue. These defects are mostly grooves that work as stress concentration factors. Once fatigue cracks initiates on the instrument surface, stress concentration factors favor nucleation, growth, and propagation of cracks (Plotino *et al.* 2009; Lopes *et al.* 2010). Initiating of fatigue crack usually occurs at the surface of a working part and it is especially vulnerable if the area with the highest stress coincide with the machining marks or miniature grooves (Kim *et al.* 2010).

b) Angle and radius of curvature

Resistance of rotary instruments to cyclic fatigue depends on the angle and radius of curvature, size and taper. Of these, radius of curvature is the dominant factor (Inan *et al.* 2007). The radius of curvature represents how abruptly or severely a specific angle of curvature occurs as the canal deviates from a straight line and NCF significantly increase as radius increases (Grande *et al*. 2006). In Figure 1 two lines are drawn along the long axes of the root canal, and two other lines are perpendicular to these lines. The angle formed by these two perpendicular lines which intersect at the circle's center is the angle of curvature, expressed in degrees and the length of these lines it's the radius. The smaller the radius, the more abrupt the canal deviation. The parameters of angle of curvature and radius of curvature are independent, so canals can have the same angle of curvature while having different radii of curvature, resulting in more abrupt curves (Pruett *et al.* 1997).

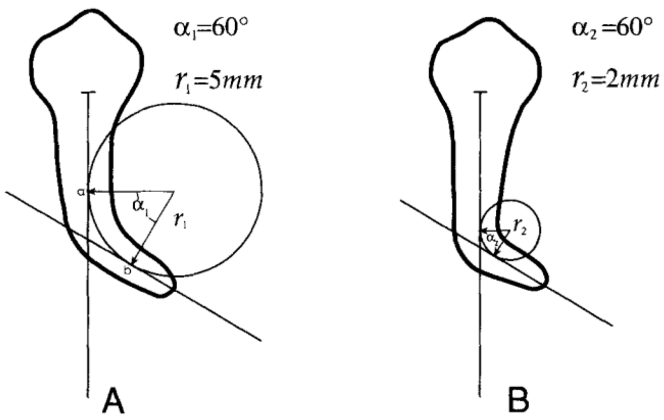

Figure 1 - Pruett's method to demonstrate the influence of radius (r) and angle of curvature (α) in canal geometry. (Pruett *et al.* 1997)

c) Rotational speed

Contrasting findings on the influence of rotational speed on cyclic fatigue of NiTi instruments were described. Pedullà and co-workers state that some studies found rotational speed did not influence the cyclic fatigue, whereas others reported that a higher rotational speed decreased cyclic fatigue resistance of endodontic NiTi instruments. These different results may have occurred because of varying test conditions, different operators and different instrument types. Therefore, the effect of rotational speed on cyclic fatigue of endodontic instruments remains unclear (Lopes *et al.* 2009; Pedullà *et al.* 2014).

1.3 M-Wire®

To enhance mechanical properties and try to overcome file separation during clinical use M-Wire® technology was developed. NiTi alloys are manufactured with 56 wt % of nickel and 44 wt % of titanium, but the nickel component of this variant alloy is 55,8 wt % with titanium equaling the vast majority of the remainder with trace elements including O,C, Fe each at approximately 0,05 wt %. This alloy undergoes a proprietary thermomechanical process, comprised of drawing the raw wire under specific tension and heat treatments at various temperatures, resulting in a material that contains three crystalline phases deformed and microtwinned martensite, R-phase and austenite. Instruments made from this wire exhibit more resistance to cyclic fatigue compared to those made of conventional NiTi whilst maintaining comparable torsional properties (Gutmann & Gao, 2012; Ye and Gao 2012).

1.4 The ProTaper Next™ system

The ProTaper Next™ system was released in the market in April of 2013 as the successor of the ProTaper Universal™ system. These rotary instruments are made of M-Wire® technology that offers greater flexibility and also provide greater resistance to cyclic fatigue. ProTaper Next™ features a rectangular cross-section design, is used with brushing movements and has an asymmetric rotation, this means that the axis of rotation differs from the center of mass and further enhances canal shaping efficiency. As a result, only two points of the rectangular cross section touch the canal wall at a time. The rotation of the off-centered cross section generates enlarged space for debris hauling (DentsplyMaillefer 2013; Elnaghy 2014).

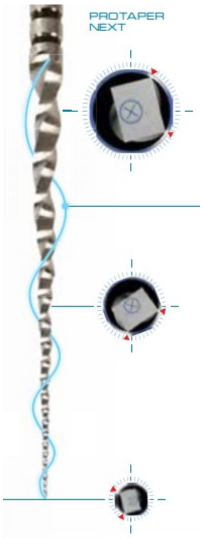

Figure 2 – The cross-section design and canal movement of ProTaper Next™ (DentsplyMaillefer 2013).

Dentsply Maillefer™ advocates that files should be single patient use for optimal cutting efficiency, no risk of cross contamination and because a single use reduces the risk of file breakage and therefore increases patient safety.

This system has five files available for shaping canals with different sizes: X1 (tip size 17 with a taper of 0,04), X2 (tip size 25 with a taper of 0,06), X3 (tip size 30 with a taper of 0,07), X4 (tip size 40 with a taper of 0,06) and X5 (tip size 50 with a taper of 0,06). These files have identification rings, in sequence, yellow, red, blue, double black and double yellow corresponding to the different sizes, respectively. This system has three different lengths available (21, 25 and 31 mm).

Figure 3 – The ProTaper Next™ system for shaping root canals (Dentsply Maillefer).

2. AIMS

The aim of this *in vitro* study is to analyze the fatigue life of ProTaper Next^{TM} instruments after clinical use and compare with files with no pre-utilizations, since manufacture recommends a single use.

Specific goals:

1 - To compare fatigue life of instruments X1, X2 and X3 after clinical use.

H0 – the number of cycles until break is alike in all instruments.

H1 – the number of cycles until break is different for X1 instrument.

H2 – the number of cycles until break is different for X2 instrument.

H3 – the number of cycles until break is different for X3 instrument.

H4 – the number of cycles until break is different for all instruments.

2 - To compare localization of fracture in instruments X1, X2 and X3.

H0 – the localization of fracture is alike in all instruments.

H1 – the localization of fracture is different for X1 instrument.

H2 – the localization of fracture is different for X2 instrument.

H3 – the localization of fracture is different for X3 instrument.

H4 – the localization of fracture is different for all instruments.

3 - To compare fatigue life of ProTaper Next^{TM} instruments after clinical use with instruments with no pre-utilizations.

For X1:

H0 – the number of cycles until break is alike in both instruments.

H1 – the number of cycles until break is different between instruments.

For X2:

H0 – the number of cycles until break is alike in both instruments.

H1 – the number of cycles until break is different between instruments.

For X3:

H0 – the number of cycles until break is alike in both instruments.

H1 – the number of cycles until break is different between instruments.

4 - To compare localization of fracture in instruments after clinical use with instruments with no pre-utilizations.

H0 – the localization of fracture is alike in all instruments.

H1 – the localization of fracture is different between instruments.

3. MATERIALS

Tree types of rotary endodontic instruments were tested in this study: X1 (17/04), X2 (25/06) and X3 (30/07) from Protaper Next™ system (Dentsply Tulsa Dental Specialties). The files were provided by the post-graduation clinic of Faculdade de Medicina Dentária da Universidade de Lisboa, after various clinical utilizations. The rotary instruments were used in several clinical cases between 5 to 8 times.

Files were allocated according to instrument type as shown in Chart 1:

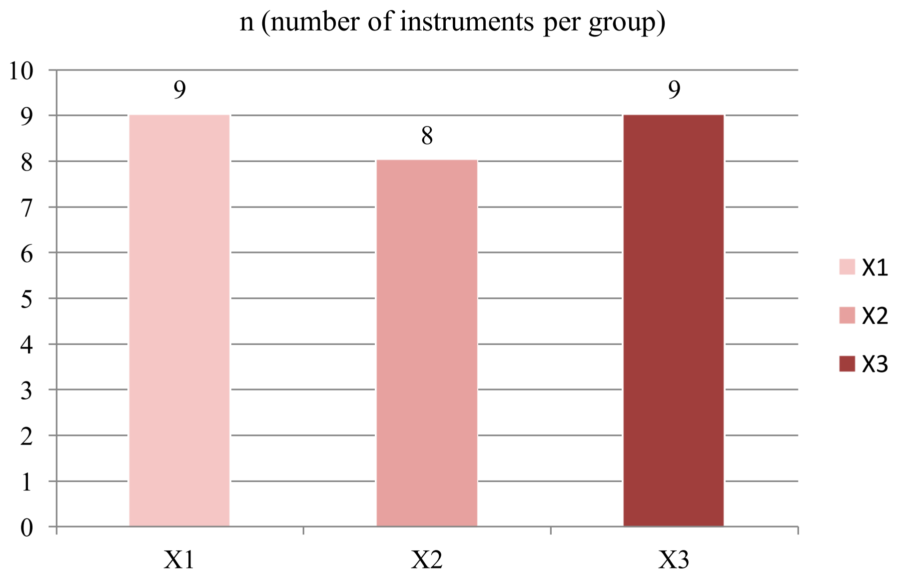

Chart 1– The number of instruments of X1, X2 and X3 used in this experimental procedure

In this *in vitro* study the motor used was the WaveOne™ (Denstply Maillefer) in ProTaper Universal program, at 300 rpm continuous rotary motion and a torque of 4 N cm.

Figure 4 – The WaveOne ™ (Denstply Maillefer) motor used in this study

4. METHODS

The fatigue life of endodontic rotary instruments was tested in a mechanical system previously created due to a partnership between the department of Endodontics in Faculdade de Medicina Dentária da Universidade de Lisboa (Lisbon Faculty of Dentistry) and the Mechanical and Industrial Engineering Department of Faculdade de Ciências e Tecnologia da Universidade Nova de Lisboa. The system tries to simulate the inner forces of a root canal, recreating the bending forces. The two parameters related to these bending forces are: the radius and angle of the curvature.

In order to compare data with Vaz 2014, who studied the ProTaper Next^{TM} instruments with no pre-utilizations, the same parameters were considered: angle of curvature - 45º and radius of curvature - 4,7mm.

Figure 5 shows a geometric drawing of the mechanical system. In (a) the instrument enters, is forced to bend and adjust to the curvature in (b) and in (c) the tip is visible. The W point represents the place where the extremity of the instrument should be in each test, to standardize instrument placement, and had a distance of 5 mm from the beginning of the curvature of the simulated root canal. To guarantee that the whole system was static, except the instrument to be tested, it was necessary to use three tighten bolts in the prototype, in order to prevent the different pieces from moving apart. The reproducibility of the tests is guaranteed by these parameters.

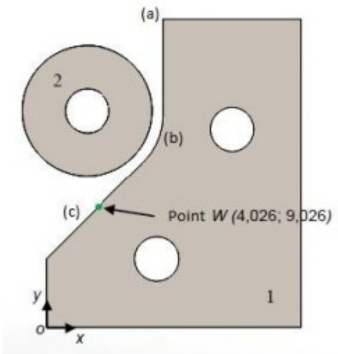

Figure 5 - Schematic representation of the mechanical system adapted from Vaz 2014.

The piece number 1 (block) was manufactured by a Computerized Numerical Control machine (CNC) and piece number 2 (washer) was manufactured from a rod of stainless steel that was machined to a diameter of 4,7 mm and hole-drilled. The stand structure is a stainless steel plate with 1,5mm thick with several folding, cutting and welding. The contra-angle of the motor WaveOne ^{TM} (Dentsply Maillefer) was fixed to the metallic stand structure with two plastic pieces. The system was all supported by a malleable screen of teflon which was fixed to the table with two staples (Figure 6). Testing time was registered with a digital chronometer manually operated, started at the moment the motor was turned on and stopped as fracture was detected visually and/or audibly.

Figure 6 – The Wave-One motor and the experimental apparatus.

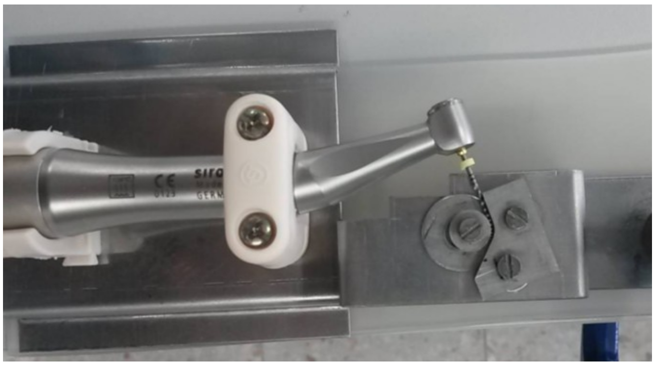

Figure 7 – The experimental apparatus close-up: headpiece and file.

4.1 Experimental procedure

The following procedure was used in all instruments:

1- Place the motor in the fixed system;
2- Place the instrument to be tested in the contra-angle and rotate the head of the contra-angle until the instrument is parallel to the table;
3- Make sure that the instrument is between pieces no. 1 and 2;
4- Ensure that the extremity of the file is well positioned at the W point and that it is perpendicular to the upper part of the block;
5- Tighten the three bolts according to the previous adjustments;
6- Turn on the WaveOne™ motor and select the ProTaper Universal programme;
7- Get the chronometer set up and ready to use;

8- Step on the pedal initiating the chronometer at the same time, until separation of the instrument occurs;
9- Stop the chronometer when the tip of the instrument fractures;
10- Remove the instrument off the contra-angle and measure the length of the instrument;
11- Repeat every step for each instrument.

All instruments were tested under the same conditions and by the same operator. The time of fracture was registered in each test (t). The NCF for each file was calculated by multiplying the time to failure, in seconds, by the rotational speed which in this study was 300 rpm:

$$\text{NCF} = \frac{300t}{60} \Leftrightarrow \text{NCF} = 5\text{t}$$

The point of fracture in relation to the tip of the instrument was determined by measuring the fractured file with a ruler.

Additionally, in order to complement further knowledge, a bibliographic research was made between January and August of 2015 using database Pubmed/Medline with a combination of the following keywords: ProTaper Next, cyclic fatigue, nickel-titanium instruments, rotary preparation and clinical use. Through evaluation of the abstract, relevant content articles were selected.

4.2. Statistical analysis

The statistical analysis was obtained using the IBM® SPSS® Statistics version 19.0.0 *software*. Descriptive statistical analysis was performed to each group of X1, X2 and X3, calculating group mean, standard deviation and variance.

Kolmogorov-Smirnov and Shapiro-Wilk tests analyzed the data. In the samples that showed normality, the parametric test t-student for independent samples was applied in groups that compare two variables. The data that showed no normality was analyzed by non parametric tests. The Kruskal-Wallis test was used to compare three variables and Mann-Whitney U test was used in groups that compare two variables. Significance was set at the 95% confidence level (Larson-Hall 2010).

5. RESULTS

Table 1 shows the results of the experimental procedure: time to fracture in seconds, fracture length in millimeters and number of cycles to fracture for each type of file.

Type of file	Time (sec)	Fracture length (mm)	NCF
$X1_1$	212,1	6	1060,5
$X1_2$	223,4	4,5	1117
$X1_3$	384,2	4,5	1921
$X1_4$	66,7	6	333,5
$X1_5$	177,7	6	888,5
$X1_6$	61,6	6	308
$X1_7$	162	7,5	810
$X1_8$	148	6	740
$X1_9$	156,8	6	784
$X2_1$	70,8	4,5	354
$X2_2$	107,1	4,5	535,5
$X2_3$	75,2	7	376
$X2_4$	85	6	425
$X2_5$	56,2	5,5	281
$X2_6$	75,4	6	377
$X2_7$	54,3	6,5	271,5
$X2_8$	54,7	6,5	273,5
$X3_1$	68,6	5,5	343
$X3_2$	60,6	4	303
$X3_3$	100,6	5	503
$X3_4$	46,9	5,5	234,5
$X3_5$	63,5	6	317,5
$X3_6$	45,9	6	229,5
$X3_7$	74,9	6	374,5
$X3_8$	72,1	6	360,5
$X3_9$	63,8	5	319

Table 1 - Results for each instrument test for time to fracture (seconds), length of the fractured tip (mm) and Number of Cycles to Fracture.

One of the aims of this study is to compare the files after clinical use with the ones with no pre utilizations. Data from Vaz 2014 study were considered since the same parameters and experimental conditions were followed. Table 2 presents the mean value of time, fracture length, NCF and the respective standard deviation for used and new files.

	Type of file	N	Mean ± St. Deviation	Variance
Time (sec)	X1 used	9	176,9 ± 95,7	9159,3
	X1 new	4	233,8 ± 36,1	1306, 1
	X2 used	8	72,3 ± 18,1	326,5
	X2 new	16	77,8 ± 9,3	87,4
	X3 used	9	66,3 ± 16,3	266,1
	X3 new	4	89,3 ± 9,5	89, 4
Length of fracture (mm)	X1 used	9	5,8 ± 0,9	0,8
	X1 new	4	3,9 ± 0,2	0,03
	X2 used	8	5,8 ± 0,9	0,9
	X2 new	16	4,0 ± 0,2	0,05
	X3 used	9	5,4 ± 0,7	0,5
	X3 new	4	4,5 ± 0,5	0,3
NCF	X1 used	9	884,7 ± 478,5	228983
	X1 new	4	1169,1 ± 180,7	32651,7
	X2 used	8	361,7 ± 90,3	8162,7
	X2 new	16	389,2 ± 46,8	2191,9
	X3 used	9	331,6 ± 81,6	6651,5
	X3 new	4	446,6 ± 47,3	2235,9

Table 2 - Presents means, standard deviation and variance of files clinically used and with no pre utilizations.

The following charts show the NCF median and variance for each file group:

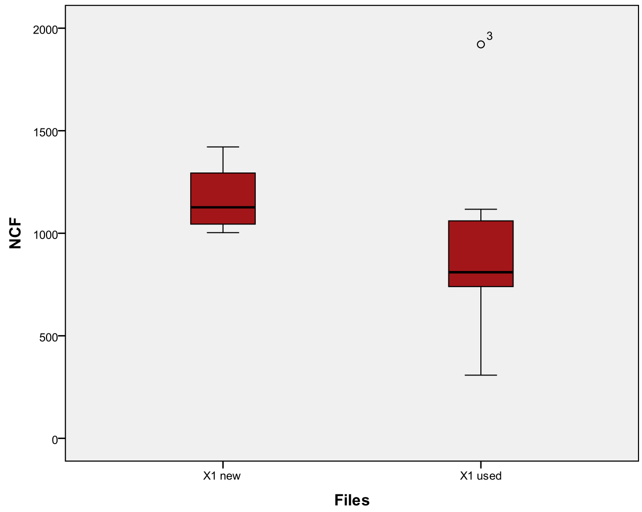

Chart 2 – NCF median and variance for X1 clinical used and with no pre utilizations

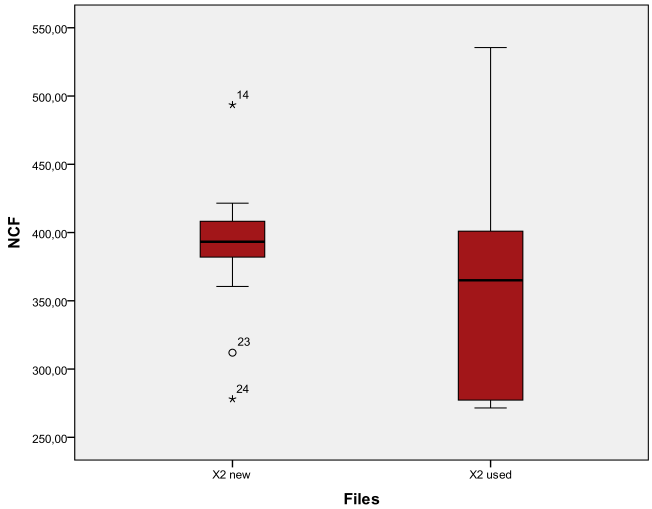

Chart 3 - NCF median and variance for X2 clinical used and with no pre utilizations

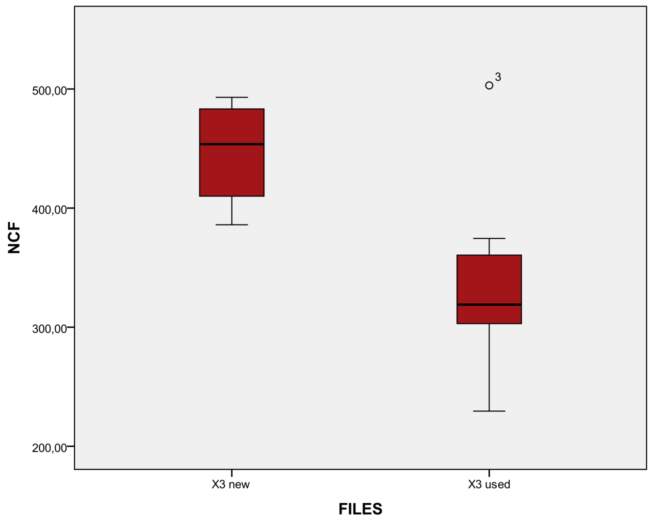

Chart 4 - NCF median and variance for X3 clinical used and with no pre utilizations

5.1 Statistical analysis

The Kolmogorov-Smirnov and Shapiro-Wilk tests were applied to NCF file data and revealed normality.

Group A: X1 and X2

Group B: X1 and X3

Group C: X2 and X3

The t-student test analyze these groups. Homogeneity of the sample was considerate, through Levene's test.

	Group A	Group B	Group C
Levene's test	0,051	0,03	0,712
sig	0,008	0,008	0,482

Table 3 - Significance of groups A, B and C

Group A and B were found to be statistically significant with a *p* value<0,05, rejecting the null hypothesis (H0) and confirming hypothesis 1.

The data regarding fracture length were analyzed by Kolmogorov-Smirnov and Shapiro-Wilk tests showing no normality so the non-parametric Kruskal-Wallis test was applied revealing no statistically differences between each type of files (*p*=0,405), retaining the null hypothesis.

In order to compare the NCF of the files already used clinically with the ones with no pre-utilizations three groups were set:

Group 1: X1 new and used

Group 2: X2 new and used

Group 3: X3 new and used

Group 1 and 3 were analyzed by parametric t-student test since the Kolmogorov-Smirnov and Shapiro-Wilk tests showed normality and because in Group 2 these tests revealed no normality the non-parametric Mann-Whitney U test was applied. In t-student test the homogeneity of the sample was considerate through Levene's test.

	Group 1	Group 2	Group 3
Levene's test	0,287	---	0,507
sig	0,283	0,142	0,025

Table 4 - Significance of groups 1, 2 and 3

Only Group 3 show a statistically significant difference between clinically used and new files (*p*=0,025), rejecting the null hypothesis. Groups 1 and 2 retain the null hypothesis.

Another aim of this study is to compare fracture length between clinically used and new files, so three groups were defined:

Group I: X1 new and used

Group II: X2 new and used

Group III: X3 new and used

The Mann-Whitney U test was applied in Groups I and III because the data showed no normality by the Kolmogorov-Smirnov and Shapiro-Wilk tests. Group II was analyzed by t-student test due to normality shown by previous tests. The difference in fracture length between instruments clinically used and new was found to be statistically significant in all cases, presenting a p value<0,05, rejecting the null hypothesis.

	Group I	**Group II**	**Group III**
Levene's test	---	0,0001	---
sig	0,003	0,001	0,041

Table 5 - Significance of groups I, II and III

6. DISCUSSION

File fracture is the main concern throughout canal shaping procedures (Kim *et al.* 2010). As previously seen, there are several factors responsible for file fracture during clinical use, with cyclic fatigue being reported as a significant cause (Elnaghy 2014).

The purpose of this study was to evaluate the cyclic fatigue resistance of clinical used ProTaper Next™ files and compare with instruments with no pre-utilizations, through the calculation of NCF. The study with ProTaper Next™ files with no pre-utilizations from Vaz in 2014 showed X1 to be significantly more resistance than X2 and X3. The same correlation occurred in this experiment, i.e., X1 instrument proved to be statistically significant more resistant than X2 and X3, rejecting the null hypothesis (H0). The X2 file was more resistant than X3, presenting a mean value of NCF slightly higher, but not significantly. Instruments with larger diameters have been found to succumb to flexural fatigue earlier than those with smaller diameters so this can explain why X1 is the most resistant file (Fife *et al.* 2004; Plotino *et al.* 2009; Gambarini *et al*. 2010; Pérez-Higueras *et al*. 2014).

The NCF of clinical used files X1, X2 and X3 showed a decrease in the mean values when compared with the files with no pre-utilizations, but only X3 proved to be significantly less resistant, rejecting the null hypothesis for this file. Literature support these findings as previous cyclic fatigue studies on other NiTi file systems reported that repeated clinical use reduced their resistance to fracture (Aydin *et al*. 2010).

Another parameter studied was the fracture length where no significant difference was found between clinically used files. A significant difference was only seen between used and new files, possibly because in the present study, the measurement was made with a ruler, and in Vaz study it was used a coordinates measuring table which would introduce more accurate data. This difference in the experiment protocol was due to the fact that coordinates measuring table was no longer available so this represents a limitation of this study. Another explanation is the fact that because in this experimental the sample was submitted to previous stress, this could generate microcracks along the instrument surface. The pre-existing defects could influence the site of fracture (Ounsi *et al.* 2007). Moreover, a designed system to simulate a root canal that does not constrain the instrument in a precise trajectory may alter bending properties of the files and therefore contribute to different fracture sites

(Plotino *et al*. 2009). The localization of the fractured segment could provide information for clinicians by identifying the most fragile portion of the instrument. However, limited knowledge exists on this subject.

Only one study was found comparing clinical used and new ProTaper Next™ files. Ertas and Capar use extracted mandibular molar and showed that the longest life span of ProTaper Next™ instruments was nine molar teeth, the shortest was three teeth, with a median life span of 5.5 teeth. However, it is referred that the variables of canal anatomy and operator could be more influential in fracture susceptibility than the instruments *per se*. Another result of their study was that X1 files had the highest separation incidence among the tested instruments. This might be due to the fact that X1 was the first file used to penetrate to the working length and to shape all the canal thirds. Thus, the X1 instrument was more likely to suffer from fatigue.

Another two studies research the cyclic fatigue for this system with files with no pre-utilizations. Although test conditions of both studies differ from the present study, the results also showed that X1 is the most resistant file to cyclic fatigue, and X2 presented to be more resistance than X3 which supports the present findings. However, in Vaz study X2 was the file with less NCF, a possible explanation for that is that the size sample for X1 and X3 was small (n=4).

Article	Testing conditions	Rotational speed	NCF (mean/st. dev)	Time (mean in sec)	Conclusions
Pérez-Higueras *et al.* 2014	60º 3 mm Synthetic oil	300	--	X1 – 56,4 X2 – 29,1 X3 – 5,3	X1 was significantly more resistance than X2 and X3. X2 more resistance than X3.
Nguyen *et al.* 2014	90º 5 mm Synthetic oil	300	X1 - 718 ± 91 X2 - 403 ± 60 X3 - 262 ± 51	--	X1 was significantly more resistance than X2 and X3. X2 was significantly more resistance than X3.

Table 6 - Summarize of the conditions and design, their results and conclusions of the two studies considered.

The effect of rotational speed on instrument fracture is related to the generation of heat, so higher speeds produce more heat and thereby induce a faster increase in the instrument temperature. This raise of temperature leads to a rapid increase in surface tension, causing precocious fatigue fracture (Lopes *et al.* 2009). Even though the rotational speed was the same in all studies, 300 rpm as recommended by the manufacturer, the synthetic oil used in the studies of Pérez-Higueras *et al*. and Nguyen *et al.* prevented the raise of temperature in files so this can mean an increase NCF of these two samples. However, the influence of rotational speed in resistance to cyclic fatigue is not clear because some studies found that this parameter did not influence the cyclic fatigue of NiTi files (Pedullà *et al.* 2013). The increase of angle and radius of curvature results in a decreased instrument lifespan (Plotino *et al.* 2010), and these factors are also different in these two studies. But as the comparisons made are between files under the same conditions, we can take under consideration these results within the limitations of different experimental procedures.

A study from Pedullà *et al.* in 2014 used X2 files from the ProTaper Next™ to research the influence of torsional preloading on cyclic fatigue, concluding that torsional preloads reduced the cyclic fatigue resistance. This corroborates that torsional and cyclic fatigue can both act together and diminish lifespan of endodontic instrument (Park *et al.* 2010; Bhagabati *et al.* 2012).

Since only one study was found evaluating the deterioration and failure of ProTaper Next™ system after clinical use, the research for this evaluation done in others systems of rotary NiTi files was taken into consideration and there has been no consensus on how many times or how long a file could be used for root canal preparation. One study reported that reusing NiTi files up to four times did not increase separation incidence. Another performed a cyclic fatigue test for NiTi files after prolonged clinical use and, although a decrease was observed for the cyclic fatigue resistance, each instrument was successfully operated ten times. In other study the conclusion was that clinical use in four molars did not increase the fracture incidence. However, there are several studies reporting that clinical use significantly reduced the cyclic fatigue resistance of rotary NiTi instruments (Inan and Gonulol 2009). Fife *et al.* reported that prolonged reuse of rotary NiTi instruments and other factors such as iatrogenic errors or misuse might be important in instrument separation, so strict recommendations are difficult to make. But in some cases such as very complex, calcified and curved canals, the instruments should be discarded after a single use or selectively discarded to increase safety in clinical practice (Pessoa *et al*. 2013).

It should be noted that the files collected for this study were used by different operators in different clinical cases. The teeth had different dentin hardness and the diameter of the canals, angle and radius of curvature were not the same in every case (Inan and Gonulol 2009). Besides that, the sample size obtained is small and heterogeneous because the files were used between 5 to 8 clinical cases, which can introduce bias in this study. The ideal test model would involve instrumentation of curved canals in natural teeth. However, in such tests a tooth can be used only once and the trajectory of the root canal changes during instrumentation, making it impossible to standardize experimental conditions, such as the intensity of stress in the rotating-bending area. Also there will always be a combination of torsional stress and cyclic fatigue when human root canals are used (Lopes *et al.* 2009; Plotino *et al.* 2010). So the creation of an artificial metal apparatus had the purpose to minimize bias.

It is also necessary to emphasize that the sample of this study was submitted to sterilization up to 8 times. This can also affect the resistance to fatigue, since sterilization, sodium hypochlorite and other solutions used in root canal treatment can possible introduce additional corrosion stress to the files, i.e., the fatigue process begins with crack initiation at the material surface and environmental conditions can modify both the crack initiation and propagation processes (Ounsi *et al.* 2007; Shen *et al.* 2012). Although this parameter always occurs when using clinically used files it is very difficult to measure.

Another factor to take into account is that this experiment engages a static cyclic fatigue test. It has been reported that static cyclic fatigue tests showed lower results compared with dynamic tests in which endodontic instruments are subjected to axial movements. The alternating compressive and tensile stresses are likely concentrated at the same area of the instrument in static tests. Therefore, higher cyclic fatigue resistance is expected in a clinical situation in which instruments are operated in a constant in and out motion (Pérez-Hygueras *et al*. 2014). This could mean that the NCF and thus the time to fracture of the sample could be higher than the observed. In future studies, the possibility to do a dynamic test should be evaluated, because this would be closer to the real movement that the instrument is submitted to during instrumentation. The analysis of a larger sample of instruments with a more controlled clinical use should also be considered to provide more scientific evidence of the conclusions.

In fact, the research related to cyclic fatigue of endodontic instruments could be improved. There is a necessity of making well-designed studies with standardized specifications to minimize uncontrolled variables and to reproduce the same conditions between researchers.

7. CONCLUSION

The knowledge of the mechanical behavior of endodontic instruments is very important for clinicians to predict clinical performance. Due to a growing tendency of reusing these instruments, for economic reasons, the aim of this study was to evaluate if it is safe to reuse ProTaper Next^{TM} system.

Within the limitations of this *in vitro* study, the results suggest that resistance to fatigue life diminishes after various clinical uses and because it is hard to detect minor defects and fractures, all instruments should be checked carefully before each use. The discard after a single use should be considered in more complex cases. A lower resistance to cyclic fatigue in larger instruments was also shown in the results, so these files in particular should be used with greater care, especially in curved canals, and discarded sooner than smaller instruments.

Because NiTi rotary instruments are widely used, the need for a standardization of testing their properties including cyclic fatigue is required to ensure the uniformity of methodology and comparable results for a safer, more efficient clinical use.

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APPENDIX

Abbreviations

CNC - computerized numerical control
NCF - number of cycles to fracture
NiTi - nickel-titanium
Ie - that is to say

Symbols

% - Percentage
n - Number of sample
p - Significance
® - Registered trademark
TM- Unregistered trademark
O – Oxygen
C – Carbon
Fe – Iron

Units

º - Degrees
ºC - Degree Celsius
mm - Millimeters
N cm - Newton centimeter
rpm - Rotations per minute
wt – Weight